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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/523,054	03/10/00	BEHERA - A	0152.00355

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EXAMINER	
DUFFY, P	

ART UNIT	PAPER NUMBER
1645	11

DATE MAILED: 09/19/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/523,054	Behera et al
Examiner	**Art Unit**
Patricia A. Duffy	1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *one* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-18* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

1. Prior to setting forth the restriction requirement, it is noted that the claims recite improper Markush Groups. M.P.E.P. 803.02 states that: Since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978); and *In re Haas*, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, *unless the subject matter in a claim lacks unity of invention* [emphasis added], *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility." In the instant case, the products and methods rely upon antibodies that bind different polypeptides, polynucleotides and structurally undefined agents that regulate ICAM-1 expression which differ in structure and origin to such an extent and require non-coextensive searches to such an extent that they are considered to lack a substantial structural feature disclosed as being essential to the disclosed utility. As such, the structurally different agents have been restricted each from the other.

Election/Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-6 and 10-12, drawn to methods of prevention of respiratory infection including RSV infection by administering an undefined therapeutic agent that down-regulates ICAM-1 expression, classified in class 424, subclass 130.1.

II. Claims 7-8, drawn to an anti-ICAM-1 antibody composition that regulates ICAM-1 expression, classified in class 530, subclass 388.22.

III. Claims 7-8, drawn to an anti-RSV antibody composition that regulates ICAM-1 expression , classified in class 530, subclass 388.3.

IV. Claims 7-8, drawn to an antisense nucleotide-based therapeutic agent that down-regulates ICAM-1 expression , classified in class 536, subclass 24.5.

V. Claims 9, 13, and 14 drawn to a method of preventing RSV infection or blocking binding of RSV to ICAM-1 by administering an effective amount of an undefined agent that interferes with the binding of RSV to ICAM-1 classified in class 536, subclass 24.5.

VI. Claims 15, 16 and 17, drawn to an anti-ICAM-1 antibody composition that blocks ICAM sites of binding, classified in class 530, subclass 388.22.

VII. Claims 15, 16 and 17, drawn to an anti-RSV antibody composition that blocks ICAM sites of binding, classified in class 530, subclass 388.3.

VIII. Claims 15, 16 and 18, drawn to an antisense nucleotide-based therapeutic agent that blocks ICAM sites of binding, classified in class 536, subclass 24.5.

3. The inventions are distinct, each from the other because of the following reasons:

Inventions II, III, IV, VI, VII and VIII are drawn to mutually exclusive and independent products such as nucleic acids, proteins, compounds of undefined structure which change the function of the coded sequence, compounds of undefined structure which regulate the expression of the coding or coded sequence and compounds that block RSV-ICAM-1 interaction. The products are distinct each from the other because they have different chemical compositions (e.g. nucleic acid, amino acid, undefined compounds) have different biological function (e.g. the nucleic acid inhibits expression, the protein performs a cellular activity, the compositions function to modify the function of the protein by regulating expression or blocking the interaction of the protein with a viral agent) and are made by different methods (e.g. chemical synthesis, recombinant expression, isolation from nature). For the foregoing reasons the products are separate each from the other. Additionally, the antibodies are separate each from the other because the claims require that they bind different structural proteins and perform different functions. As such, each antibody is distinct each from the other. moreover, the Markush members and not linked by a substantial structural feature and are separately patentable. It is noted that the claims currently

encompass both nucleic acids and proteins and undefined compounds, should applicants elect one of Inventions II, III, IV, VI, VII and VIII, applicants are required to amend the claims to reflect only the elected subject matter.

Inventions (II or III or IV) and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids can be used in materially different process of use such as, *in situ* chromosome mapping, methods of detecting the nucleic acid using hybridization methods and diagnosis of disease by detection of nucleic acid levels. In the instant case the anti-ICAM-1 antibody can be used for identifying ICAM-1 expressing cells as a cell marker, administered as a therapeutic, in a method of diagnosis of inflammatory diseases, in a method of screening for agents which modulate ICAM-1 expression on a cell *in vitro* or in a method of purification of the protein from cells. In the instant case, the anti-RSV antibody can be used in a method of detection of infection by detection of the RSV in culture or in a method of purification of the virus or viral proteins.

Inventions (VI or VII or VIII) and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be

used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids can be used in materially different process of use such as, *in situ* chromosome mapping, methods of detecting the nucleic acid using hybridization methods and diagnosis of disease by detection of nucleic acid levels. In the instant case the anti-ICAM-1 antibody can be used for identifying ICAM-1 expressing cells as a cell marker, administered as a therapeutic, in a method of diagnosis of inflammatory diseases, in a method of screening for agents which modulate ICAM-1 expression on a cell *in vitro* or in a method of purification of the protein from cells. In the instant case, the anti-RSV antibody can be used in a method of detection of infection by detection of the RSV in culture or in a method of purification of the virus or viral proteins.

Inventions I and V are separate and distinct each from the other because they are drawn to different methods which have different goals as evidenced by their preambles (I- prevention of prevention of respiratory infection including RSV infection by administering an undefined therapeutic agent that down-regulates ICAM-1 expression or V- a method of preventing RSV infection or blocking binding of RSV to ICAM-1 by administering an effective amount of an undefined agent that interferes with the binding of RSV to ICAM-1), utilize different reagents with different functions (I- expression modulators and V- blocking interaction of ICAM-1 with RSV) and have different final outcomes. It is noted that each of the methods now recite generic agents or compounds with undefined structure. Should applicants add method claims reciting the use of anti-ICAM-1 antibodies, anti-RSV

antibodies or antisense DNA, each of these methods will be restricted each from the other because the protocols for gene therapy and antibody and protein therapy are materially different and separate. In addition, neither reagent or method is required for the implementation of the other method. For the foregoing reasons the methods of inventions are separate and distinct from each other.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, as shown by their different classification, and in the absence of a restriction would place an undue search and examination burden on the examiner, restriction for examination purposes as indicated is proper.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

6. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy, Ph.D. whose telephone number is (703) 305-7555. The examiner can normally be reached on Tuesday-Saturday from 10:00 AM to 6:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308-3909.

Patricia A. Duffy, Ph.D.
September 18, 2001

Patricia A. Duffy, Ph.D.
Primary Examiner
Group 1600